

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MICROSPHERIX LLC,

Plaintiff,

v.

MERCK SHARP & DOHME CORP., MERCK
SHARP & DOHME B.V., AND ORGANON
USA, INC.,

Defendants.

Civil Action No. 2:17-cv-03984-CCC-MF

**DECLARATION OF DAVID N. DRAPER
IN SUPPORT OF PLAINTIFF'S
RESPONSIVE CLAIM CONSTRUCTION
BRIEF**

Document Filed Electronically

DAVID N. DRAPER, ESQ., of full age, hereby declares as follows:

1. I am an attorney registered to practice in the States of New York and New Jersey and in this Court and am a partner with the firm Kirkland & Ellis LLP, attorneys for Plaintiff Microspherix LLC ("Microspherix") in the above-captioned action.

2. I submit this Declaration in support of Microspherix's Responsive Claim Construction Brief.

3. Attached hereto as **Exhibit 11** is an excerpted and annotated copy of the deposition transcript of Dr. Kinam Park, dated December 10, 2020.

4. Attached hereto as **Exhibit 12** is a true and correct copy of excerpts from Drug Delivery: Fundamentals & Applications (Anya M. Hillery & Kinam Park, eds., 2nd ed. (2017)) (Exhibit 6 of the deposition of Dr. Kinam Park).

5. Attached hereto as **Exhibit 13** is a true and correct copy of U.S. Patent No. 10,413,504 to de Graaff et al., issued on September 17, 2019.

6. Attached hereto as **Exhibit 14** is a true and correct copy of the 37 C.F.R. § 41.202 Suggestion of Interference regarding U.S. Patent Application No. 14/711,658 and U.S. Patent No. 8,722,037, from the file history of U.S. Patent Application No. 14/711,658, dated May 13, 2015, and retrieved from the United States Patent and Trademark Office (“USPTO”) Public Patent Application Information Retrieval system at <https://portal.uspto.gov/pair/PublicPair> on July 19, 2017.

7. Attached hereto as **Exhibit 15** is a true and correct copy of B. Perot et al., “Spectrum Shape Analysis Applied to Radioactive Waste Gamma-Ray Spectroscopy,” in Advanced Monte Carlo for Radiation Physics, Particle Transport Simulation and Applications (2001), pp. 413–18.

8. Attached hereto as **Exhibit 16** is a true and correct copy of the Amendment and Response to Office Action from the file history of U.S. Patent Application No. 14/711,658, dated November 8, 2016, and retrieved from the USPTO Public Patent Application Information Retrieval system at <https://portal.uspto.gov/pair/PublicPair> on July 19, 2017.

9. Attached hereto as **Exhibit 17** is a true and correct copy of excerpts from Merck Sharp & Dohme Corp., Merck Sharp & Dohme B.V., and Organon USA, Inc.’s Second Amended Invalidity Contentions, dated August 17, 2020 (Designated Highly Confidential – Outside Counsel Only Information).

10. Attached hereto as **Exhibit 18** is a true and correct copy of the Amendment to Support Request for Continued Examination (RCE) Under the Provisions of 37 CFR § 1.114 and Supplemental Information Disclosure Statement from the file history of U.S. Patent Application No. 10/592,725, dated July 20, 2010, and retrieved from the USPTO Public Patent Application Information Retrieval system at <https://portal.uspto.gov/pair/PublicPair> on January 12, 2021.

11. Attached hereto as **Exhibit 19** is a true and correct copy of U.S. Patent Application Publication No. 2019/0216725 to Barnett et al., published July 18, 2019.

12. Attached hereto as **Exhibit 20** is a true and correct copy of Paper 1, Petition for *Inter Partes* Review in IPR2018-00393, dated December 22, 2017.

13. Attached hereto as **Exhibit 21** is a true and correct copy of excerpts from Mosby's Medical, Nursing, & Allied Health Dictionary, Sixth Edition (2002).

14. Attached hereto as **Exhibit 22** is a true and correct copy of U.S. Patent No. 6,514,193 to Kaplan, issued on February 4, 2003.

15. Attached hereto as **Exhibit 23** is a true and correct copy of the Product Monograph of Implanon NXT™ (2012), bearing bates production range MICRO0064096–MICRO0064149.

16. Attached hereto as **Exhibit 24** is a true and correct copy of Eun-Seok Park et al., “Biodegradable Polyanhydride Devices of Cefazolin Sodium, Bupivacaine, and Taxol for Local Drug Delivery: Preparation, and Kinetics and Mechanism of in Vitro Release,” J. Controlled Release 52:179–189 (1998).

17. Attached hereto as **Exhibit 25** is a true and correct copy of Alejandro Sánchez et al., “*In Vivo* Study of the Tissue Distribution and Immunosuppressive Response of Cyclosporin A-Loaded Polyester Micro- and Nanospheres,” Drug Delivery 2:21–28 (1995).

18. Attached hereto as **Exhibit 26** is a true and correct copy of G. De Rosa et al., “Influence of the Co-Encapsulation of Different Non-Ionic Surfactants on the Properties of PLGA Insulin-Loaded Microspheres,” J. Controlled Release 69:283–295 (2000).

19. Attached hereto as **Exhibit 27** is a true and correct copy of Jackson E. Fowler, Jr. et al., “Evaluation of an Implant That Delivers Leuprolide for 1 Year for the Palliative Treatment of Prostate Cancer,” Urology 55:639–642 (2000).

20. Attached hereto as **Exhibit 28** is a true and correct copy of Sarat C. Chattaraj et al., “Biodegradable Microparticles of Influenza Viral Vaccine: Comparison of the Effects of Routes of Administration on the In Vivo Immune Response in Mice,” J. Controlled Release 58:223–232 (1999).

21. Attached hereto as **Exhibit 29** is a true and correct copy of María J. Alonso et al., “Biodegradable Microspheres as Controlled-Release Tetanus Toxoid Delivery Systems,” Vaccine 12(4): 299–306 (1994).

22. Attached hereto as **Exhibit 30** is a true and correct copy of excerpts from Physicians’ Desk Reference, 54th Edition (2000).

23. Attached hereto as **Exhibit 31** is a true and correct copy of the Electronic Acknowledgement Receipt, Application Data Sheet, Declaration, Specification, Claims, Abstract, and Drawings from the file history of U.S. Patent Application No. 14/711,658, dated May 13, 2015, and retrieved from the USPTO Public Patent Application Information Retrieval system at <https://portal.uspto.gov/pair/PublicPair> on January 14, 2021.

24. Attached hereto as **Exhibit 32** is a true and correct copy of excerpts from the USPTO’s Cooperative Patent Classification Subclass A61K, Version 2021.01, and retrieved from the USPTO’s website at <https://www.uspto.gov/web/patents/classification/cpc/html/cpc-A61K.html#A61K49/00> on January 12, 2021.

25. Attached hereto as **Exhibit 33** is a true and correct copy of excerpts from the USPTO’s Cooperative Patent Classification Subclass A61L, Version 2021.01, and retrieved from the USPTO’s website at <https://www.uspto.gov/web/patents/classification/cpc/html/cpc-A61L.html#A61L31/16> on January 12, 2021.

26. Attached hereto as **Exhibit 34** is a true and correct copy of the Notice of Allowance, Examiner-Initiated Interview Summary, Issue Classification, and Search Notes from the file history of U.S. Patent Application No. 14/711,658, dated March 9, 2017, and retrieved from the USPTO Public Patent Application Information Retrieval system at <https://portal.uspto.gov/pair/PublicPair> on January 14, 2021.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

By:

Dated: January 14, 2021
New York, NY

/s/ David N. Draper

David N. Draper